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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,260	ELLIOTT ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8, 10-11, 43-45, 56-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,11,43-45,56 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1a. Receipt of Applicants' amendment and arguments filed on 13 January 2005, is acknowledged. Claims 1-3 have been amended. Claims 9, 12-42, 46-55 and 58 are canceled. Claims 1-8, 10-11, 43-45, 56-57 are pending and are under consideration.

1b. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed 01/13/2005:

(I) The objection of claims 1-8, 10-11, 43-45 and 56-57 for reciting non-elected SEQ ID Nos, is withdrawn, since these claims no longer recite these SEQ ID Nos.

(II) The rejection of claims 1-8, 10-11, 43-45 and 56-57 made under 35 U.S.C. § 112, second paragraph, for not reciting hybridization conditions, is withdrawn, because these claims now recite specific hybridization conditions.

Claim rejections-35 USC § 101:

3a. The rejection of claims 1-8, 10-11, 43-45 and 56-57, made under 35 USC § 101 is maintained for reasons of record set forth in the office action mailed on 13 July 2004.

Applicants argue that the specification contend that the instant specification asserts a specific and substantial utility for the claimed invention that would be credible. Applicants also argue that the instant specification discloses GPCR proteins, and that one skill in the art readily recognizes that

GPCR proteins inherently possess a specific utility. Applicants submit an abstract that that discusses the importance of GPCR as therapeutic targets. Applicants argue that the instant specification provides a number of specific, exemplary uses for the GPCR of the instant invention.

Applicants' arguments have been fully considered, but are deemed unpersuasive. Firstly, the credibility of the asserted utility is not disputed, however, the asserted utility is neither specific nor substantial. Applicants (as well as the authors of the submitted abstract) are correct in that G-protein coupled receptors are important therapeutic targets for drug design, however, members of this family is functionally diverse and they bind to a large variety of ligands, such as photons, neurotransmitters and hormones. Furthermore, GPCR family proteins are involved in cancer, cardiac dysfunction, diabetes, central nervous system disorders, obesity, inflammation, and pain, Thus, knowledge of the specific ligand that binds to each G-protein coupled receptor and/or the physiological condition that is affected by said binding, is required in order for it to be useful in a diagnostic or therapeutic manner, (see Ulloa-Aguirre et al; Archives of Medical Research, vol. 30, pages 420-435, 1999; especially abstract and pages 423-424). The claimed GPCR needs further characterization, to ascertain its specific and substantial utility, however, further characterization is part of the invention and until it had been undertaken, the claimed invention is not complete and is not supported by a specific asserted utility or a well established utility. Although the instant specification discloses a list of exemplary and disparate diseases or conditions that the claimed invention might be useful in treating or

diagnosing, the specification fails to establish a direct link between any of the recited diseases or conditions and the claimed invention.

3b. Claims 1-8, 10-11, 43-45 and 56-57 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants argue that the specification provides experimental protocols for testing GPCR activity in Example 8, pages 89-90 and that one of skill in the art can readily compare the activity of the GPCR of the instant invention to any polypeptide set forth in the claims.

This argument is not found persuasive, because, the specification does not provide a specific activity for the GPCR of the instant invention. Example 8, discloses a general protocol of how to process transgenic mice and how to isolate single cell suspensions from said mice. This example does not provide any specific information about the GPCR of the instant invention. . The instant specification only discloses the amino acid sequence for the protein encoded by the claimed nucleic acid, it does not disclose an activity for it, neither does it establish a nexus between the claimed nucleic acid and a physiological condition. Therefore the skilled artisan would not know how to use the nucleic acid, comprising the nucleotide sequence set forth in SEQ ID NOS:1 or the protein encoded, thereby.

With respect to the rejection of claims 1-8, 10-11, 43-45 and 56-57 under 35 U.S.C. 112, first paragraph, for lacking written description for all of the encompassed variants, applicant present the following argument. Applicants argue that since the claims now recite specific hybridization conditions, the nucleotide sequences recited in the amended claims are adequately described since the specification describes said specific hybridization conditions.

This argument is not found persuasive. Although the claims now recite the hybridization conditions, the claims fail to recite functional limitations. Therefore, the single species disclosed (i.e SEQ ID NO:1), fails to adequately describe all of the encompassed nucleic acids. Furthermore, the specification does not disclose a nucleotide sequence that encodes a polypeptide that is 70% identical to the polypeptide of SEQ ID NO:2, as recited in claim 2. While the degeneracy of the genetic code accommodates some variation in the nucleotide sequence, the extent of variation disclosed go far beyond alternate codons for the same amino acid. A skilled artisan would expect that the variation in the polynucleotide sequence would at best code for a polypeptide that has impaired function and at worst be either nonfunctional or an entirely different product from that of the claimed invention. Therefore, it would be impossible to predict with certainty the effect of a substitution, insertion, or deletion of a series of nucleotides, or even one nucleotide, on the encoded product. In order to make an accurate assessment of the modifications encompassed by these claims and to determine the function of the encoded protein would require undue experimentation.

With respect to amino acid modifications, the instant specification does not provide the guidance needed to predictably alter by 30%, in SEQ ID NO:2, with any reasonable expectation that the resulting protein will have the desirable biological activity.

Priority:

5a. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is not supported by none of the parent applications, because, although the polypeptide of SEQ ID NO:2 and the nucleic acid of SEQ ID NO:1, are disclosed in the parent applications, the parent applications fail to provide a specific and substantial asserted utility or a well established utility for the claimed invention.

Accordingly, the subject matter defined in claims 1-8, 10-11, 43-45 and 56-57, is afforded an effective filing date of 14 February 2002, which is the filing date of the current application.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior 02/14/2002, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 02/14/2002.

Claim rejections-35 USC § 102:

6a. Applicants intention to file a declaration under 37 C.F.R §1.131, to prove that the claimed invention was conceived prior to the publication date of the reference, is acknowledged.

6b. The rejection of claims 1-8, 10-11, 43-45 and 56-57 under 35 U.S.C § 102(a) as being anticipated by (WO 01/36473 published May/2001; WO 01/36471 published May/2001, WO 73029 published Octobert/2001; WO 74904 published October/2001), is maintained for reasons of record set forth in the office action mailed on13 July 2004, pages 11-12. the effective filing date of the current application is 14 February 2002, (see directly above) which is after the publication dates of the references. Therefore, this rejection is maintained.

New Rejections:

Claim Rejections - 35 U.S.C. § 101:

7a. Claims 5-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 5-7 are drawn to " a host cell comprising...", which encompasses the host cell, as it occurs in nature, for example, as a gene therapy patient. However, since Applicants do not intend to claim a naturally occurring products amendment of the claims to show the hand of man would obviate this rejection. It is suggested that claims be amended to recite " an isolated host cell..... .....". Appropriate correction is required.

8a. Claim 8 is rejected under 35 U.S.C. 1 12, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites "GPCR...", which renders the claim unclear, because more than one polypeptide can be known for the same acronym. Applicant is advised to recite the full name of the polypeptide corresponding to this acronym in the first independent claim to obviate this rejection.

Conclusion:

9. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
18 April 2005

JANET ANDRES
PRIMARY EXAMINER